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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,753	06/27/2003	Karl-Heinz Bozung	01-1088-3-C2	7182

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EXAMINER	
KARPINSKI, LUKE E	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/608,753	BOZUNG ET AL.	
	Examiner	Art Unit	
	LUKE E. KARPINSKI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *29 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/29/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of terminal disclaimers and IDS filed 9/29/2008 and 10/21/2008 is acknowledged.

Change in Examiner

The examination of this application will now be conducted by Luke Karpinski; contact information can be found at the end of this action.

Claims

Claims 11-14 have been canceled.

Claims 1-10 are currently pending and under consideration in this action.

Rejections

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

New Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,481,435 to Hochrainer et al.

Hochrainer et al. disclose, inhalers comprising one or more actives for inhalation (col. 4, lines 26-30), a preferred combination of actives as tiotropium and fomoterol (col. 6, lines 38-41), salmeterol as an alternative betamimitic (col. 5, line 35), tiotropium bromide (col. 5, lines 19-30), and the addition of excipients to said compositions (col. 7, lines 37-38).

Regarding the method of making said compositions, said methods are necessarily practiced, as the combination in formulated into a concentrate, the components must be mixed together.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1, 2, 5, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over "How to effectively control your patient's dyspenea COPD management: Achieving bronchodilation to Gross.

Applicant Claims

Applicant claims a composition comprising glycopyrronium bromide or a compound of the structure of instant claim 1 and a betamimetic selected from the list recited in instant claim 1.

Applicant further claims said structure as an anticholinergic, specifically tiotropium, said betamimetic as formoterol or salmeterol, and said compositions as inhaled pharmaceuticals.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Gross teaches compositions for inhalation (entire disclosure), including tiotropium, the addition of a beta2 agonist, and salmeterol as a long acting beta2 agonist (page 185 col. 1, line 10 to page 186 col. 1, line 14), as claimed in claims 1, 2, 5, and 9.

Ascertainment of the differences between the prior art and the claims

(MPEP 2141.01)

Gross does not explicitly disclose an example wherein the claimed

components are combined into a single composition. However, Gross does suggest that a beta2-agonist be added to ipatropium and teaches that tiotropium is a anticholinergic, which should have therapeutic advantages over ipatropium and that salmeterol is a long-acting beta2-agonist.

Gross also does not explicitly teach a method of making said compositions, however the combination of said components is suggested.

Finding of prima facie Obviousness Rational and Motivation

(MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teaching of a combination of anticholinergics and beta2-agonists along with the teaching of tiotropium as a potentially better anticholinergic and salmeterol as a beta2-agonist and produce a composition comprising salmeterol and tiotropium. In a prior art reference it is not necessary for all of the possible compositions to be exemplified in order for the art to render an invention obvious.

Regarding claim 10, it would have been obvious to one of ordinary skill in the art at the time of the invention to practice the method of claim 10 because Gross suggests the combination of said components and the only way to combine said components is to mix them.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed

invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

2. Claims 3, 4, and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over "How to effectively control your patient's dyspenea COPD management: Achieving bronchodilation to Gross, in view of "Chronic obstructive pulmonary disease: new opportunities for drug development" to Barnes.

Applicant Claims

Applicant claims are delineated above.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

The teachings of Gross are delineated above and incorporated herein.

Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)

Gross does not teach tiotropium bromide as claimed in claims 3, 4, and 6-8. This deficiency in Gross is cured by Barnes. Barnes teaches tiotropium bromide as an inhaled anticholinegic (page 1, col. 2).

Gross also does not teach formoterol as a beta2-agonist, This deficiency in Gross is cured by Barnes. Barnes teaches formoterol as a beta2-agonist, For treating COPD.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Regarding claims 3, 4, and 6-8, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the compositions of Gross with tiotropium bromide as taught by Barnes in order to produce the invention of instant claims 3, 4, and 6-8.

One of ordinary skill in the art would have been motivated to do this because Barnes teaches the tiotropium bromide has a long duration and will be suitable for once a day dosing. Therefore it would have been obvious to utilize the tiotropium bromide of Barnes, with the compositions of Gross in order to provide a pharmaceutical which only requires dosing once a day.

Regarding claims 6, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the compositions of Gross with formoterol as taught by Barnes in order to produce the invention of instant claim 6.

One of ordinary skill in the art would have been motivated to do this because Gross teaches the combination of a anticholinergic and a beta2-agonist and Barnes teaches formoterol as a beta2-agonist. Therefore it would have been obvious to utilize

the tiotropium bromide of Barnes, with the compositions of Gross in order to provide a pharmaceutical which only requires dosing once a day.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

3. Claims 1, 2, 5, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Bronchodilators in the therapy of chronic obstructive pulmonary disease" to Rees.

Applicant Claims

Applicant claims are delineated above.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Rees teaches beta2-agonists, including salmeterol and formoterol (page 139 second paragraph), anticholinergics, including tiotropium (page 140, last paragraph), and the combination of said compounds (page 142, last paragraph) as pertaining to claims 1, 2, 5, 9, and 10.

Ascertainment of the differences between the prior art and the claims

(MPEP 2141.01)

Rees does not explicitly disclose an example wherein the claimed components are combined into a single composition, however, Rees does suggest that the combination of said components could be combined.

Finding of prima facie Obviousness Rational and Motivation

(MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to select each component and combine them as instantly claimed because Rees suggests that beta2-agonists and anticholinergics can be combined and teaches salmeterol and formoterol as beta2-agonists and tiotropium as an anticholinergic. In a prior art reference it is not necessary for all of the possible compositions to be exemplified in order for the art to render an invention obvious.

Regarding claim 10, it would have been obvious to one of ordinary skill in the art at the time of the invention to practice the method of claim 10 because Rees suggests the combination of said components and the only way to combine said components is to mix them.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

4. Claims 3, 4, and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Bronchodilators in the therapy of chronic obstructive pulmonary disease" to Rees, in view of "Chronic obstructive pulmonary disease: new opportunities for drug development" to Barnes.

Applicant Claims

Applicant claims are delineated above.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

The teachings of Rees are delineated above and incorporated herein.

Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)

Rees does not teach tiotropium bromide as claimed in claims 3, 4, and 6-8. This deficiency in Rees is cured by Barnes. Barnes teaches tiotropium bromide as an inhaled anticholinegic (page 1, col. 2).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Regarding claims 3, 4, and 6-8, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the compositions

of Rees with tiotropium bromide as taught by Barnes in order to produce the invention of instant claims 3, 4, and 6-8.

One of ordinary skill in the art would have been motivated to do this because Barnes teaches the tiotropium bromide has a long duration and will be suitable for once a day dosing. Therefore it would have been obvious to utilize the tiotropium bromide of Barnes, with the compositions of Rees in order to provide a pharmaceutical which only requires dosing once a day.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

5. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Chronic obstructive pulmonary disease: new opportunities for drug development" to Barnes.

Applicant Claims

Applicant claims are delineated above

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Barnes teaches inhaled tiotropium bromide (page1, col. 2), salmeterol and formoterol (page 2, col. 2), and the combination of the two (page 2, col. 2) as claimed in claims 1-10.

Ascertainment of the differences between the prior art and the claims (MPEP 2141.01)

Barnes does not explicitly disclose an example wherein the claimed components are combined into a single composition, however, Barnes does teach each component and suggest the combination thereof.

Finding of prima facie Obviousness Rational and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to select each component and combine them as instantly claimed because Barnes suggests that salmeterol and formoterol can be combined with anticholinergics and that tiotropium is a long-acting anticholinergic. In a prior art reference it is not necessary for all of the possible compositions to be exemplified in order for the art to render an invention obvious.

Regarding claim 10, it would have been obvious to one of ordinary skill in the art at the time of the invention to practice the method of claim 10 because Rees suggests the combination of said components and the only way to combine said components is to mix them.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Claims 11-14 are canceled.

Claims 1-10 are rejected.

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUKE E. KARPINSKI whose telephone number is (571)270-3501. The examiner can normally be reached on Monday Friday 9-5 est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LEK

/Mina Haghighatian/
Primary Examiner, Art Unit 1616